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Re-evaluation Note REV2009-09

Endosulfan

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Overview

Endosulfan is one of the active ingredients under re-evaluation by Health Canada's Pest Management Regulatory Agency (PMRA). The purpose of this Re-evaluation Note is to notify registrants, pesticide regulatory officials and the Canadian public of interim label amendments to be implemented for endosulfan products. These changes are required to limit dietary, worker and environmental exposure pending completion of the risk assessments and development of a risk-management strategy.

In August 2002, the PMRA published Re-evaluation Note REV2002-04, *Endosulfan*, announcing that it would re-evaluate the insecticide endosulfan. REV2002-04 also informed registrants, regulatory officials and the Canadian public that the recently announced risk-management plan of the United States Environmental Protection Agency would be acceptable to Bayer and Makhteshim, the manufacturers of endosulfan technical products for Canada.

In June 2004, the PMRA published Proposed Acceptability for Continuing Registration PACR2004-21, *Re-evaluation of Endosulfan - Interim Mitigation Measures* proposing certain measures in advance of completing the full re-evaluation, as a precautionary approach to mitigate potential dietary, worker and environmental risks. Based on many comments from growers, registrants and regulatory officials to PACR2004-21, the PMRA determined the use pattern for endosulfan that would serve as the basis for completing the re-evaluation. The PMRA reviewed available information and published Re-evaluation Note REV2007-13, *Preliminary Risk and Value Assessments of Endosulfan,* in October 2007 for public comment.

In March 2009, the PMRA then published Re-evaluation Note REV2009-03, *Re-evaluation of Endosulfan Interim Mitigation Measures*, responding to comments received on the proposed risk mitigation measures and providing a revised proposal to limit dietary, worker and environmental exposure to endosulfan, pending development of a risk management strategy. This current Re-evaluation Note provides a summary of comments received on REV2009-03 and the PMRA's response to these comments in Appendix I. Comments received during the consultation process did not result in substantial changes to the proposed regulatory decision as described in the REV2009-03. Appendix II presents label amendments that are now required to enact the interim risk mitigation measures. Appendix III is a list of currently registered products.

Risk mitigation measures that are now required include:

- additional protective equipment, precautions, and packaging of wettable powder (WP) formulations in water soluble bags to protect mixers, loaders and applicators;
- a restricted-entry interval (REI) to protect those re-entering treated sites;
- reduced rates and numbers of applications for some crops;

- removal of several crops from product labels (alfalfa, clover, sunflower, spinach, succulent beans, succulent peas); for wettable powder products, use on field tomatoes, sweet corn, dry beans and dry peas must also be removed; and

- additional advisory label statements and buffer zones to reduce potential surface water contamination.

Next Steps

The PMRA is currently reviewing comments and new data received in response to REV2007-13. The PMRA will propose a risk-management strategy for endosulfan in a future document along with the PMRA's assessment of the comments and additional information received as well as issues related to health, environment and the Toxic Substances Management Policy.

List of Abbreviations

a.i.	active ingredient
cm	centimetre
EC	emulsifiable concentrate
g	gram
h	hour
ha	hectare
kg	kilogram
km	kilometre
L	litre
m	metre
PHI	preharvest interval
PMRA	Pest Management Regulatory Agency
PPE	personal protective equipment
REI	restricted-entry interval
WP	wettable powder

Appendix I Comments and Responses

1.0 Comments With Respect to the Environment

1.1 Comment

Large buffer zones are still a concern for horticultural crops. PMRA does not acknowledge some drift mitigation technologies used in Ontario: air induction nozzles, 80° flat fan nozzles, tower/smart sprayers, drift reducing nozzles.

Response

The PMRA recognizes that farmers can perceive buffer zones as impractical or logistically difficult to implement. To that end, the Agency has embarked on a consultative process aimed at developing a habitat protection policy that will protect important habitats and support sustainable pest management strategies in a way that also considers potential impacts on growers and allows our agricultural and forestry industries to be competitive. This will include consideration of "best management" practices such as recent improvements in nozzle technology. Unfortunately, the PMRA has not yet been able to review drift reduction data for low drift nozzles and therefore we are not able to provide buffer zone reductions for their use at this time. In the future, the PMRA intends to examine the effectiveness of using low drift nozzles and would be interested in reviewing any information/data the Ontario Ministry of Agriculture, Food and Rural Affairs might have on these nozzles.

1.2 Comment

Why doesn't the buffer zone table mention grapes, sugar beets and Japanese yew?

Response

In the table listing the buffer zones, sugar beets should be added to same box as celery and grapes should be added to the same box as apples, pear, apricot, cherry, peach and plum under the crop column (see revised buffer zone table in Appendix II). Buffer zones would not be required for Japanese yew if it is a greenhouse non-food use.

2.0 Comments With Respect to Value

2.1 Comment

Is Use-site Category 6 (greenhouse non-food use) correct for Japanese yew?

Response

The registered labels for endosulfan products formulated as a wettable powder include the label claim for control of the black vine weevil on ornamentals grown both outdoors and in greenhouses. In addition to the generic claim for black vine weevil control on ornamentals (which includes yews), specific use directions are provided on the registered labels for the control of black vine weevil on Japanese yews (outdoors and in greenhouses). The PMRA recognizes that Japanese yew is typically produced outdoors. However, it is possible that yew container stock could be maintained for a period of time

in a greenhouse (for example, hoop house or tall tunnel) for short periods of time (for example, prior to shipping, etc.) and that limiting the application to yews (outdoors) may have an impact to the ornamental industry.

2.2 Comment

For strawberries, a spray volume of 2000 L/ha is quite large and is beyond spraying to run-off. It is suggested that the labels be revised to indicate "apply in sufficient water for thorough coverage".

Response

The labels will be revised to state the spray volume should be as follows:

"Apply in sufficient water for thorough coverage".

2.3 Comment

Bean beetle has been an increasing problem in snap beans. They can move into the crop 3 to 4 days prior to harvest and cause huge economic loss. Growers rely on endosulfan to help manage Mexican bean beetle, since it has a short preharvest interval and growers consider it one of the more effective products.

Response

The technical registrants do not support the use of endosulfan products formulated as wettable powders on beans (dry and succulent). The use of endosulfan products formulated as emulsifiable concentrates on succulent (snap) beans was also not supported. As support was not indicated for succulent (snap) beans, this crops was not included in the interim use pattern.

The registered alternatives to endosulfan for the control of Mexican bean beetle on succulent beans as of June 2009 are as follows: carbaryl, diazinon, dimethoate, malathion and trichlorfon. However, the foliar use of diazinon on beans is to be phased out. Trichlorfon use on beans is not supported by the registrant and is to be removed from the registered labels as outlined in Proposed Re-evaluation Decision PRVD2008-14, *Trichlorfon* and Re-evaluation Decision RVD2008-27, *Trichlorfon*. Carbaryl, dimethoate and malathion are currently under re-evaluation.

The preharvest intervals for the registered alternative active ingredients to endosulfan as of June 2009 (excluding those to be discontinued, or proposed for discontinuation) are as follows: carbaryl (3 or 5 days); malathion (1 day); dimethoate (7 days). The preharvest interval for endosulfan products on beans is 2 days. The PMRA acknowledges that there are limitations to the registered alternative active ingredients to endosulfan including longer pre-harvest intervals for carbaryl and dimethoate.

2.4 Comment

If endosulfan uses are to be withdrawn, a graduated, measured response is encouraged, taking into account the impacts on pest management in commodity specific situations. In some situations, there would be few effective, or no registered alternatives to control certain pests.

Response

The currently registered uses for endosulfan may be restricted or lost due to the following:

- Voluntary discontinuation of a registered product which has unique uses; or
- Voluntary discontinuation of a use which is on one registered product label but is not on other registered product labels; or
- Technical registrant(s) may not support uses at the initiation of a re-evaluation; or
- As a result of re-evaluation, a regulatory decision may be made to mitigate risk through discontinuing a use which has risk concerns.

A transition strategy is a workplan for developing alternative pest management tools for a a specific use of an active ingredient which is critical for production of the crop and for which viable alternative active ingredients are lacking. For certain crops identified in the value review of endosulfan, transition strategies have previously been initiated in response to the phase out of other active ingredients (for example, azinphos-methyl, terbufos, diazinon). Those uses of endosulfan will be considered in transition strategies that have already been initiated. If a transition strategy has not yet been initiated for a particular use, the need for one will be reviewed and discussed with stakeholders.

Appendix II Interim Label Amendments for Products Containing Endosulfan

NOTE: This use pattern summarizes risk mitigation measures required for endosulfan products following public consultation on the preliminary risk assessments and interim measures proposed in PACR2004-21 and REV2009-03. It is NOT intended to replace existing use directions on product labels.

The label amendments presented below do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Additional information on labels of currently registered products should not be removed unless it contradicts the label statements below.

COMMON NAME: Endosulfan

CHEMICAL NAME: 6,7,8,9,10,10-hexachloro-1,5,5a,6,9,9a-hexahydro-6,9-methano-2,4,3-benzodioxathiepin-3-oxide

FORMULATION TYPE:
EC emulsifiable concentrate
WP wettable powder packaged in water soluble bags.

SITE CATEGORIES:
Greenhouse Food Crops (Use-site Category 5)
Greenhouse Non-food Crops (Use-site Category 6)
Terrestrial Food Crops (Use-site Category 14)
Structural (Use-site Category 20)
Outdoor Ornamentals (Use-site Category 27)

Engineering Controls for Wettable Powder Formulations:

- All wettable powder formulations are to be packaged in water soluble bags.

Personal Protective Equipment

a. **Workers using high-pressure handwand equipment**
Wear coveralls over a long-sleeved shirt and long pants, chemical-resistant footwear, chemical-resistant gloves, and an approved organic vapour respirator during application. In addition to this protective equipment, wear a chemical-resistant apron during mixing/loading, cleanup, repair and all other handling activities.

b. **Applicators using airblast equipment on pome and stone fruit crops**
Applicators using airblast equipment on pome and stone fruit crops must either:

(i) use an enclosed and wear a long-sleeved shirt, long pants, shoes plus socks and either an approved organic vapour respirator or an enclosed cab that provides as much respiratory protection as an organic vapour respirator. When exiting the cab in the treated area, the applicator must wear coveralls, chemical-resistant

footwear, chemical-resistant headgear and an approved organic vapour respirator. Those PPE must be taken off before re-entering the cab and stored in a chemical-resistant container to prevent contamination of the inside of the cab;
OR
(ii) use an open cab and wear chemical-resistant coveralls, chemical-resistant headgear, chemical-resistant gloves and an approved organic vapour respirator.

c. **Early entry into the treated area**
If entry into treated areas is required (i.e. prior to the specified restricted-entry interval [REI]), workers must wear coveralls over a long-sleeved shirt and long pants, chemical-resistant gloves, shoes plus socks and either goggles or a face shield.

d. **All other scenarios (mixers/loaders/applicators, during cleanup and repair activities)**
Wear a long-sleeved shirt, long pants, shoes plus socks, chemical-resistant gloves, and an approved organic vapour respirator during mixing/loading, cleanup, repair, application and all other handling activities (where not specified in the previous scenarios [a. to c. above]). In addition to this protective equipment, wear a chemical-resistant apron during mixing/loading, application of dips, cleanup and repair activities.

To Mitigate Contamination of Aquatic Environments the Following Label Amendments Must be Added to the Designated labels

For Use-site Category 5, Greenhouse Food Crops, the Following Label Statements Must Be Added

Environmental Hazards

TOXIC to aquatic organisms.

Directions for Use

DO NOT allow effluent or runoff from greenhouses containing this product to enter lakes, streams, ponds or other waters.

For Use-Site Category 14, Terrestrial Food Crops, the Following Label Statements Must Be Added

Environmental Hazards

TOXIC to aquatic organisms, birds, and small wild mammals.

TOXIC to bees exposed to direct treatment, drift, or residues on flowering crops or weeds. **DO NOT** apply this product to flowering crops or weeds if bees are visiting the treatment area. Minimize spray drift to reduce harmful effects on bees in habitats close to the application site.

TOXIC to certain beneficial insects. Minimize spray drift to reduce harmful effects on beneficial insects in habitats next to the application site such as hedgerows and woodland.

To reduce runoff from treated areas into aquatic habitats, avoid application to areas with a moderate to steep slope, compacted soil, or clay.

Avoid application when heavy rain is forecast.

Contamination of aquatic areas as a result of runoff may be reduced by including a vegetative strip between the treated area and the edge of the water body.

To minimize the release of endosulfan into the environment due to volatilization, endosulfan should only be applied on cool mornings and evenings when air temperatures are 15°C or lower. To further reduce volatilization to the atmosphere, incorporation into the soil should occur concurrently with applications.

Directions for Use

As this product is not registered for the control of pests in aquatic systems, **DO NOT** use to control aquatic pests.

DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.

Field sprayer application:
DO NOT apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE) fine classification. Boom height must be 60 cm or less above the crop or ground.

Airblast application:
DO NOT apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** direct spray above plants to be treated. Turn off outward pointing nozzles at row ends and outer rows. **DO NOT** apply when wind speed is greater than 16 km/h at the application site as measured outside of the treatment area on the upwind side.

DO NOT apply by air.

Buffer zones:

Use of the following spray methods or equipment **DOES NOT** require a buffer zone: hand-held or backpack sprayer and spot treatment.

The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands) and estuarine/marine habitats.

Method of Application	Crop		Buffer Zones (metres) Required for the Protection of:			
			Freshwater Habitats of Depths:		Estuarine/Marine Habitats of Depths:	
			Less than 1 m	Greater than 1 m	Less than 1 m	Greater than 1 m
Field sprayer*	Cucumber, squash, melon, pumpkin, eggplant, pepper, tomato, potato, strawberry		90	40	120	120
	Bean		85	35	120	120
	Broccoli, brussels sprouts, cabbage, cauliflower, lettuce, rutabaga, turnip, peas, corn		75	30	120	120
	Celery, sugar beet		50	20	120	120
Airblast	Apples, pear, apricot, cherry, peach, plum and grape.	Early growth stage	70	60	90	80
		Late growth stage	60	50	80	70

* For field sprayer application, buffer zones can be reduced by using drift reducing spray shields. When using a spray boom fitted with a full shield (shroud, curtain) that extends to the crop canopy, the labelled buffer zone can be reduced by 70%. When using a spray boom where individual nozzles are fitted with cone-shaped shields that are no more than 30 cm above the crop canopy, the labelled buffer zone can be reduced by 30%.

Uses for Endosulfan

Use of endosulfan for Domestic Class products is to be discontinued. The following must be added to the labels of Commercial Class products containing endosulfan.

> This product is not to be used in and around homes or other residential areas such as parks, school grounds and playing fields. It is not for use by homeowners or other uncertified users.

Use of endosulfan for the following crops must be removed from labels:

- Alfalfa, clover
- Field corn
- Sunflower
- Spinach
- Succulent beans
- Succulent peas
- Wettable powder uses on field tomatoes, sweet corn, dry beans and dry peas

Use of endosulfan on the following sites may continue, with the indicated rates and restricted-entry intervals. **This use pattern *summarizes* risk mitigation measures required for endosulfan products, such as the maximum application rate, number of applications per season, re-entry intervals. The information in the table below is NOT intended to replace existing use directions on product labels unless the product label indicates a greater application rate, number of applications, shorter REI, etc. than identified below.**

Site	Formulation and Rate[1]	Restricted-Entry Interval[2, 3]
Use-site Category 5, Greenhouse Food Crops		
Cucumber, tomato	WP and EC formulations: Apply 500–750 g a.i./ha. (Do not exceed 600 g a.i./1000 L of water for application with high-pressure handwand equipment.)	WP and EC formulations: 48 hours
Lettuce, pepper	EC formulation: Apply 600 g a.i./ha. (Do not exceed 600 g a.i./1000 L of water for application with high-pressure handwand equipment.)	EC formulation: 48 hours
Use-site Category 6, Greenhouse Non-food Crops		
Ornamentals	EC formulations: Apply 500–700 g a.i./1000 L of water. (Do not exceed 600 g a.i./1000 L of water for application with high-pressure handwand equipment.) WP formulations: Apply 500 g a.i./1000 L of water. (Do not exceed 600 g a.i./1000 L of water for application with high-pressure handwand equipment.)	WP and EC formulations: 48 hours

Site	Formulation and Rate[1]	Restricted-Entry Interval[2, 3]
Japanese yew	WP formulation: Apply 750 g a.i./1000 L of water (Do not apply using high-pressure handwand equipment.)	
Use-site Category 14, Terrestrial Food Crops		
Apple, pear (Eastern Canada)	WP formulation: Apply 500–750 g a.i./1000 L. For white apple leafhopper and potato leafhopper, apply 1300 g a.i./ha. Do not exceed 2800 g a.i./ha per season.	WP formulation: 4 days
Apple, pear (Western Canada)	WP formulation: Apply 375–500 g a.i./1000 L of water. For white apple leafhopper and potato leafhopper, apply 1300 g a.i./ha. Do not exceed 2800 g a.i./ha per season.	WP formulation: 4 days
Apricot, cherry, plum, peach	Do not exceed 2800 g a.i./ha per season. **Foliar treatment:** WP formulation: Apply 375–750 g a.i./1000L of water. **Trunk/limb treatment:** WP and EC formulations: Apply 700–750 g a.i./1000 L of water to bark on trunk and scaffold limbs. Do not exceed 600 g a.i./1000 L for application with high-pressure handwand equipment.	WP formulation: 4 days EC formulation: 48 hours
Peach (preplant treatment)	EC formulation: Dip roots and crown in a solution of 500 g a.i./100 L of water prior to planting.	EC formulation: 48 hours
Bean (do not apply to succulent beans)	EC formulation: Apply 600–1000 g a.i./ha/application. Do not exceed two applications per season.	EC formulation: 48 hours
Broccoli, Brussels sprouts, cabbage, cauliflower	WP and EC formulations: Apply 500–875 g a.i./ha/application. Do not exceed two applications per season.	WP formulation: 9 days EC formulation: 4 days
Use-site Category 14, Terrestrial Food Crops		
Lettuce (field, head)	WP and EC formulations: Apply 800–875 g a.i./ha/application. Do not exceed two applications per season.	WP formulation: 4 days EC formulation: 48 hours
Celery	WP and EC formulations: Apply 800–875 g a.i./ha/application. Do not exceed 1100 g a.i./ha per season.	WP formulation: 4 days EC formulation: 48 hours

Site	Formulation and Rate[1]	Restricted-Entry Interval[2, 3]
Corn (sweet)	EC formulation: Apply 1100–1700 g a.i./ha/application. Do not apply more than once per season.	EC formulation: 10 days for all activities except for hand detasseling (17 days) and hand harvesting (50 days).
Cucumber, squash, melon, pumpkin	WP and EC formulation: Apply 500–600 g a.i./ha/application. Do not exceed 2200 g a.i./ha/season. Do not exceed four applications per season.	WP formulation: 3 days EC formulation: 48 hours
Eggplant, pepper	WP and EC formulations: Apply 500–1200 g a.i./ha/application. Do not exceed 2200 g a.i./ha per season. Do not exceed two applications per season.	WP formulation: 48 hours EC formulation: 48 hours
Grape	WP formulations: Apply 500 g a.i./1000 L of water. Do not exceed 1250 g a.i./ha/application. Do not exceed two applications per season.	WP formulation: 48 hours
Tomato	EC formulation: Apply 600–1200 g a.i./ha/application. Do not exceed 2200 g a.i./ha per season. Do not exceed four applications per season.	EC formulation: 48 hours
Peas (canning, seed) (do not apply to succulent peas)	EC formulation: Apply 600–800 g a.i./ha/application. Do not exceed two applications per season.	EC formulation: 48 hours
Potato	WP and EC formulations: Apply 500–875 g a.i./ha/application. Do not exceed 2200 g a.i./ha per season. Do not exceed four applications per season.	WP formulation: 48 hours EC formulation: 48 hours
Use-site Category 14, Terrestrial Food Crops		
Rutabaga, turnip	WP and EC formulations: Apply 800–875 g a.i./ha/application. Do not apply more than two applications per season.	WP formulation: 4 days EC formulation: 48 hours
Strawberry	WP and EC formulations: Apply 1000–2000 g a.i./ha/application. Do not exceed 4000 g a.i./ha per season. Do not apply more than two applications per season. Spray volume: Apply in sufficient water for thorough coverage.	WP formulation: 5 days EC formulation: 48 hours
Sugar beet	EC formulations: Apply 800–1100 g a.i./ha/application. Do no apply more than once per season. Do not feed treated foliage to livestock.	EC formulation: 48 hours

Site	Formulation and Rate[1]	Restricted-Entry Interval[2, 3]
Use-site Category 20, Structural		
Food processing plant (outdoor areas)	WP formulation: Apply 250 g a.i./22.5 kg bait.	N/A
Use-site Category 27, Ornamentals Outdoor		
Ornamental trees and shrubs	EC Formulation: Apply 500–700 g a.i./1000 L of water. WP Formulations: Apply 500 g a.i./1000 L of water. Do not exceed 600 g a.i./1000 L of water for application with high-pressure handwand equipment. Do not exceed 2800 g a.i./ha.	WP formulation: 4 days EC formulation: 48 hours
Japanese yew	EC Formulation: Apply 760 g a.i./1000 L of water. Do not apply using high-pressure handwand equipment. WP formulation: Apply 750 g a.i./1000 L of water. Do not apply using high-pressure handwand equipment.	WP formulation: 4 days EC formulation: 48 hours

[1] Rate range for a given site represents a summary of all registered rates for endosulfan products, regardless of formulation type. Registered rates for specific products may differ, but fall within the specified range.

[2] Do not enter or allow worker entry into treated areas during the REI.

[3] Where the proposed REI is longer than existing preharvest interval (PHI), the PHI will be increased to match the REI.

Appendix III Registered endosulfan products in Canada as of 29 June 2009[1]

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee
21712	Technical	Makhteshim Agan of North America Inc.	Thionex (Endosulfan) Technical	Solid	95%
24993	Technical	Bayer CropScience Inc.	Endosulfan Technical Active Insecticide	Solid	96%
25675	Manufacturing Concentrate	Bayer CropScience Inc.	Thiodan Manufacturing Use Product	Wettable Powder	50%
14617	Commercial	United Agri Products Canada Inc.	Thionex 50W Wettable Powder Insecticide	Wettable Powder	50%
15333	Commercial	Makhteshim Agan of North America Inc.	Thionex 50WP Endosulfan Commercial Insecticide	Wettable Powder	50%
15747	Commercial	Bayer CropScience Inc.	Thiodan 4EC Insecticide Liquid Emulsifiable Concentrate	Emulsifiable Concentrate	400 g/L
23453	Commercial	Makhteshim Agan of North America Inc.	Thionex EC (Endosulfan) Insecticide	Emulsifiable Concentrate	400 g/L

[1] excluding discontinued products or products with a submission for discontinuation.